



Innovative Medicines Initiative

IMI's 6th Call for proposals Procedures & Practicalities

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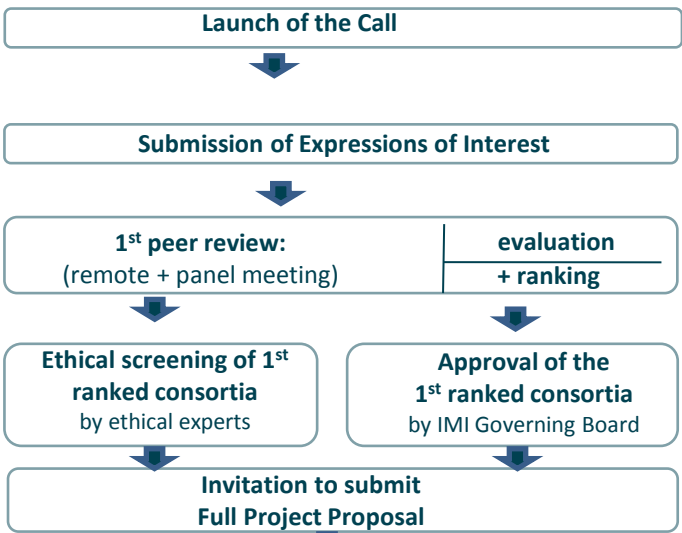


efpia*

Call 6: Key steps and timelines



Stage 1



24 May

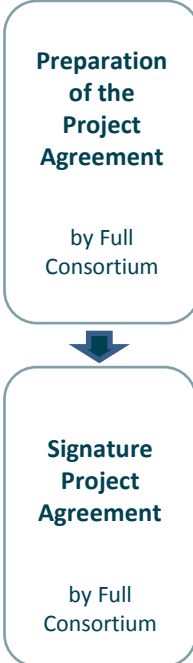
9 July

Panel meeting 25-27 July

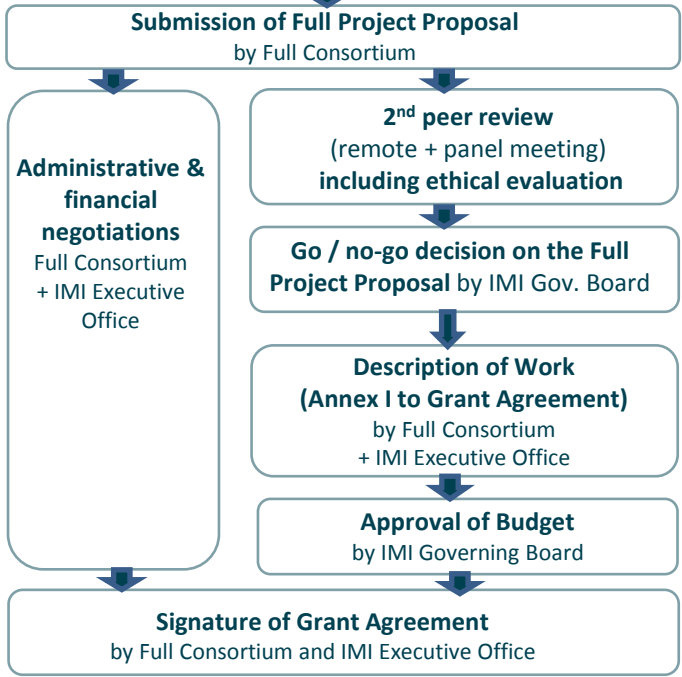
End July – early August

Early August

Stage 2



Contract negotiation



10 October

Panel meeting 29-30 October

Early November

End December



Submission of Expressions of Interest



Submission of separate Expressions of Interest (EoI) for each of the following (sub)topics:

- **Subtopic 1A:** Establishment of clinical investigator network, surveillance and epidemiology programs & innovative trials design
- **Subtopic 1B:** Conduct of clinical trials supporting the development of GSK 1322322
- **Topic 2:** Creating new knowledge and sharing data to boost antibiotic R&D



Subtopic 1A EoI: key points to consider



- Indicative budget for IMI-JU beneficiaries: € 5 M
- WP1: - will be in charge of open calls to include additional beneficiaries as needed
 - will work with similar WPs in other ND4BB topics to ensure cross-topic collaboration and dissemination
- Attention to be paid to expectations from investigators and sites forming the investigators network (GCP and high-quality clinical microbiology lab)
- Merge with subtopic 1B for the preparation of Topic 1 FPP



Subtopic 1B EoI: key points to consider



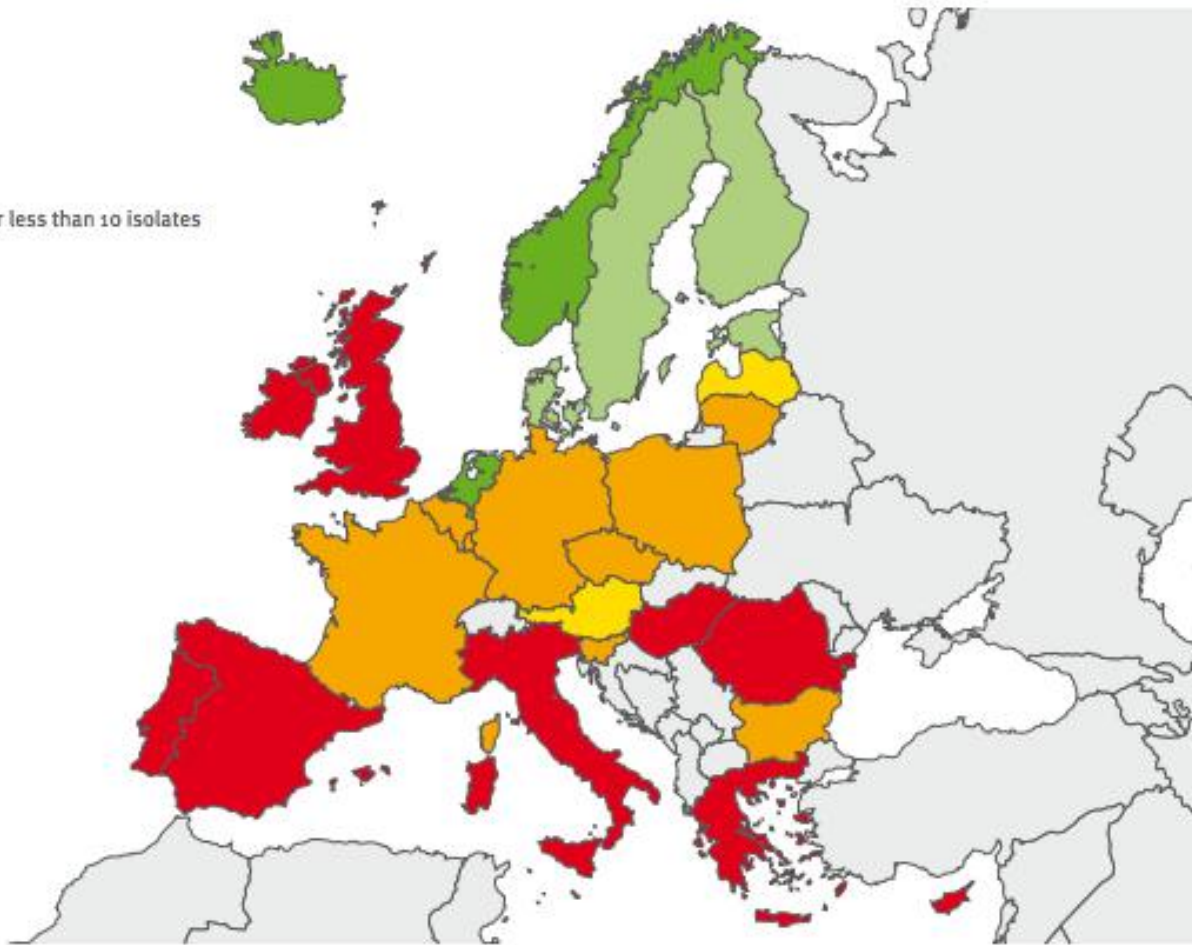
- Indicative budget for IMI-JU beneficiaries (€ 88 M)
 - clinical studies: € 48-53 M
 - *CRO subcontracting*: € 20 M
 - *Biomarkers/endpoints*: € 15-20 M
- 2 trials at the initiation of the project (WP5A and WP5C)
- 2 additional trials (WP5B and WP5D):
 - to be defined later according to milestones completion
 - might include additional partners selected by open calls handled by the consortium with IMI JU guidance
- Sites/investigators must fulfill specified requirements
- **Geographic distribution of MRSA**



Subtopic 1B: Geographical distribution of multiresistant Staphylococcus aureus

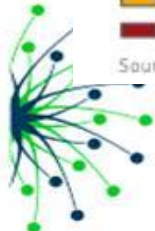


- < 1%
- 1% to < 5%
- 5% to < 10%
- 10% to < 25%
- 25% to < 50%
- ≥ 50%
- No data reported or less than 10 isolates
- Not included



- Non-visible countries
- Liechtenstein
 - Luxembourg
 - Malta

Source: EARS-Net. Only data from countries reporting more than 10 isolates are shown.

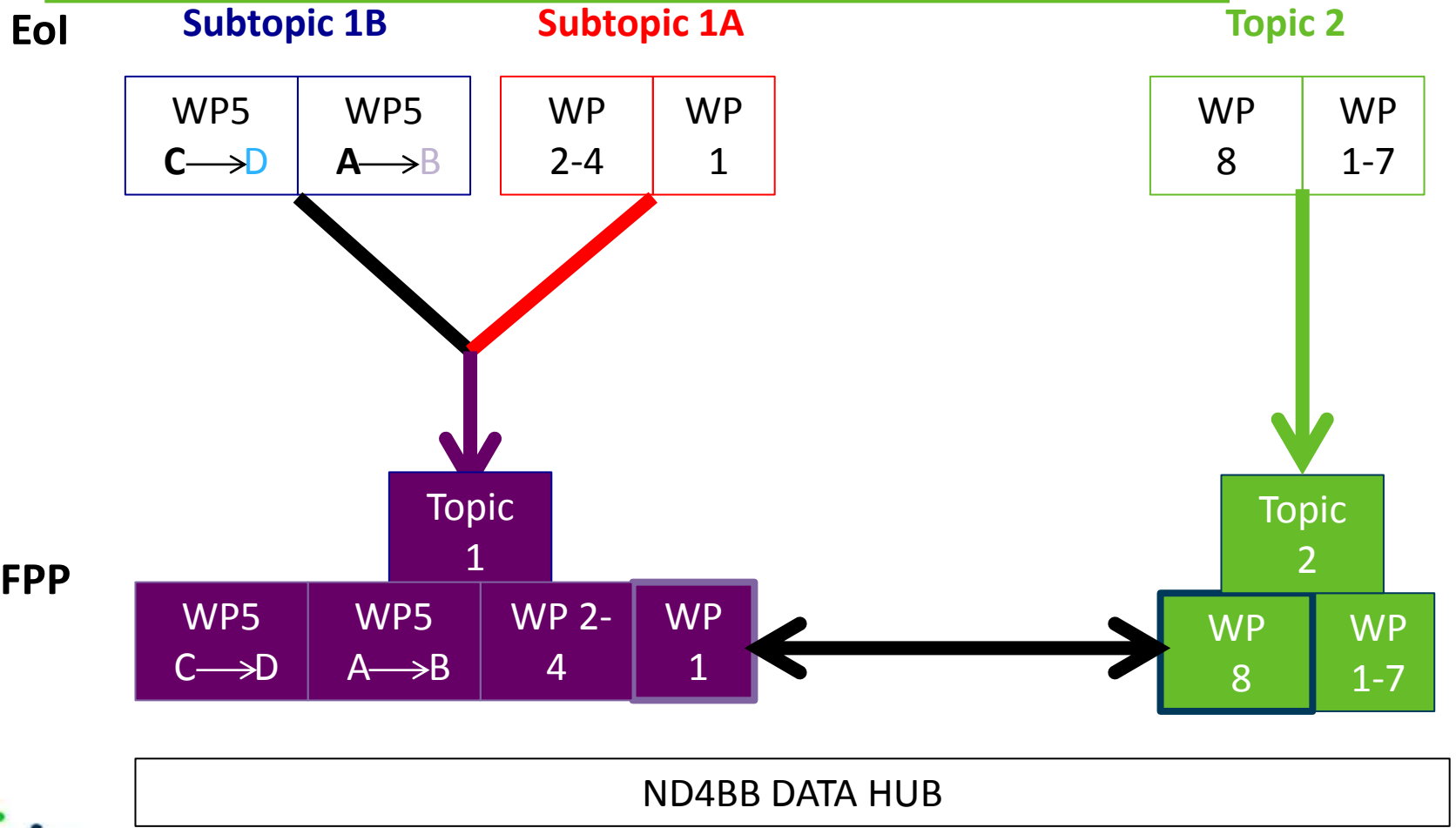


Topic 2: key points to consider

- Indicative budget for IMI-JU beneficiaries: € 16 M
- 8 workpackages
- WP8: will lead ND4BB cross-topic collaboration and dissemination



Links between (sub) topics of Call 6



Evaluation and ranking of Expressions of Interest



- Peer-review evaluation and ranking using the same peer-review process as for Call 5
- New EoI Guidance/Template and Evaluation form to accommodate the specific case of clinical trial centres (*re section partnership – individual participants*)
- The evaluation panel may recommend to merge the first-ranked consortium with other applicants' consortium(a) for the preparation of the Full Project Proposal (FPP)
- The first-ranked EoIs are screened by ethical experts to provide guidance on key ethical questions to be addressed in the FPP



Preparation and evaluation of Full Project Proposals



- The first-ranked consortia for subtopic 1A and subtopic 1B are merged and invited to prepare the Topic 1 FPP together with the EFPIA consortium
- The first-ranked consortium for Topic 2 is invited to prepare the topic 2 FPP together with the EFPIA consortium
- The FPPs of Topic 1 and Topic 2 are evaluated by experts' panels including ethical experts for go/no-go recommendation to the IMI Governing Board (GB) (same procedure as for Call 5)
- Following the GB decision, successful consortia are invited to finalize negotiations and to sign project agreements and grant agreements



Questions?



Contact us

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